

OCT 10 1996

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EXHIBIT 1

510(k) SUMMARY

P.F.C.* Σ Uni-compartmental Knee System

Johnson and Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

1. Contact Person

Anne M. Griffin, Associate Regulatory Affairs Specialist, (508) 828 - 3107.

2. Name of Device

Proprietary Name:	P.F.C.* Σ Uni-Compartmental Knee System
Common Name:	Unicompartmental Knee Prosthesis
Classification Name:	Knee joint Femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II by 21 CFR §888.3530

3. Device Classification

Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis has been placed into Class II by FDA (21 CFR §888.3530).

4. Substantial Equivalence

The P.F.C.* Σ Uni-Compartmental Knee System is substantially equivalent in design, materials and principle of operation to the P.F.C.* Uni-compartmental Knee System currently marketed by Johnson and Johnson Professional, Inc. The test data indicate that the modified device, the P.F.C.* Σ Knee system, is substantially equivalent to the predicate device. The materials used conform to ASTM standards.

5. Indications for Use

The P.F.C.* Σ Uni-compartmental Knee System is indicated for use as a uni-compartmental knee replacement for patients suffering from severe pain and disability due to structural damage caused by advanced femoral-tibial uni-compartmental degenerative arthritis resulting from primary osteoarthritis or trauma. The device is also indicated for use in patients with osteochondritis dissecans of the femoral or tibial condyle. The system is indicated for use only with bone cement.

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6. Physical Description

The P.F.C.* Uni-compartmental Knee System is a uni-compartmental knee replacement consisting of a femoral component of cobalt-chromium-molybdenum alloy, and either an all-plastic tibial component of ultra-high molecular weight polyethylene, or an alternative modular tibial component comprised of a titanium-6 aluminum-4 vanadium alloy tray with a modular UHMWPE insert.

7. Technological Characteristics as compared to Predicate Device

A Table of Similarities and Differences is attached as Table I.

The two devices utilize the same materials. All materials conform to ASTM standards.

8. Performance Testing

The following testing was carried out for a determination of substantial equivalence:

Surface Finish Analysis
Tibial Insert and Tibial Tray Interlock Testing
Femoral-Tibial Contact Area Analysis
Contact Stress Calculation

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TABLE I OF EXHIBIT I

TABLE OF SIMILARITIES AND DIFFERENCES

Similarities and Differences Table for Femoral component

	Min. fixation peg cross- sectional area	Undercut on fixation pegs	Longitudinal fixation peg channels	Condylar geometry
P.F.C. Uni- system(predicate device)	Same	No	Yes	Same
P.F.C. Σ Uni- system	Same	Yes	No	Same

Similarities and Differences Table for Insert and All UHMWPE Components

	Assembly mechanism: Insert into tray	Minimum 6 mm UHMWPE thickness	M/L topo- graphy	A/P topo- graphy	Chamfer
P.F.C. Uni- system (predicate device)	Same	Yes	Same	More conform- ing	On Anterior portion
P.F.C. Σ Uni-system	Same	Yes	Same	Less conform- ing	On Posterior and Anterior portions

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